

## UNITED STATES PATENT AND TRADEMARK OFFICE



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09 674,090	03 01 2001	Yoav Fichen	107674	1528

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Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

Application No.	Applicant(s)		
09/674,090	YOAV EICHEN	YOAV EICHEN	
Examiner	Art Unit		
Jeffrey Siew	1656		

### -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the making date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S C § 133) Any reply received by the Office later than three months after the mailling date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1 704(b). Status 1) Responsive to communication(s) filed on 09 January 2002 2b) This action is non-final. 2a) This action is FINAL. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-42 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-42 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11)[☐ The proposed drawing correction filed on <u>09 January 2002</u> is: a)[☐ approved b) ☐ disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☑ All b) ☐ Some \* c) ☐ None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 4) Interview Summary (PTO-413) Paper No(s). 5) Notice of Informal Patent Application (PTO-152) 1) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Other 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_\_

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### DETAILED ACTION

The title of the invention is not descriptive. A new title is required that is clearly
indicative of the invention to which the claims are directed.

The following I suggested. A System for Detecting Biological Moieties in a Sample Nucleation Center Forming entities.

#### Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 1/9/02 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

# Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34,36 & 42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The amended phrase "to **one or more** of at least two electrodes **onto** on the substrate" renders claims 1-34,36 & 42 confusing. It is unclear as to what the distinction is between the other phrase "to **one or more** of at least two electrodes and **onto** on the substrate". Moreover, it is unclear as to physical limitation described in the phrases. It is unclearas to whether the moiety bind to either electrode or substrate. Moreover it is unclear as to whether the electrode bound to the substrate.

### Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9,17-25, 30 & 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Mrocskowski et al (US5,284,748 Feb, 8, 1994).

Mrocskowski et al teach a method for detecting the occurrence of binding or complex forming reaction between specific substances by utilizing a binding reaction to modify an electric circuit (see whole doc. esp. abstract). They teach a diagnostic element with a biogenic substance e.g. antigen coated with onto a non-conductive based between a pair of electrical conductors. Antibodies with gold or platinum i.e. nucleation sites are reacted with antigen to be bound (see also col. 9 line 26). The particles form aggregates of electrically conductive particles each modify the circuit. The particles are then coated with conductive substance. The device is used for assessing antibodies and antigens in blood serum of human patient (see also col. 5 line 60 to col. 6 line 12). They teach that the nucleation sites may be gold (see col.2 line 47). In Figure 1 &2 layer 23 and 24 form positive and negative terminals or electrodes (see col. 4 line 59) They test conductivity with an ohmmeter functionally connected to layers 23 & 24 of figure 1 &2. (see col. 4 line 56). They teach that channels have a width of 10 microns. Figure 8 shows a device with multiple reactions sites in columns and rows. (see col. 10 line 47-60). They also teach the reducing agent hydroquinone solution for coating (see col. 15 line 26).

5. The response filed 1/9/02 has been fully considered and deemed not persuasive. The response states that Mrocskowski is different from the invention in three critical aspects-1) Mrocskowski et al's teach electrodes that are spaced with a gap whereas the instant invention does not; 2) Mrocskowski et al teach that the pair of substances e.g. antigen and antibody must bind in order to form the conductive bridge whereas the instant inention does not require association of plurality of complexes; 3) Mrocskowski et al teach coating with electrically

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conductive substance whereas the instant invention does not coat. The claims do not recite such negative limitations and reasonably read on Mrocskowski et al's device and method. While claims are read in light of the specificaition, limitations of the specification are not read into the claims. Although the preferred embodiments may not require the limitations discussed in Mroscskowski et al, the claims still read on the prior art. The terms substance and nucleation center forming entities and reagents comprising monomers reasonably encompass Mroscksowski et al's teachings. It is suggested that positive or negative limitations be incorporated to distinguish Mroscsksowski, provided the specification supports such limitations. As the primary reference is maintained, the 103 rejections over Mroscksowski et al are similarly maintained. Regarding the 103 rejection over Hisada, one of ordinary skill in the art would have been motivated to apply Hisada et al's design to Mroscksowski et al's device to lower the malfunctioning error from output noise in circuitry which would have provided a greater sensitivity to the detecting targets in Mroscksowski et al's device. A reasonable expectation of success would have been found as the electrode structure of Mrosckowski et al device. The teachings of Yang provide for the advantages of better conduction. The further teachings of Yang uses do not teach away from the advantages that one of ordinary skill in the art would have been motivated to apply in order to provide greater conduction for the detection of targets in Mrosckowski et al's device. The rejections are maintained.

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## Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-16 & 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mrocskowski et al (US5,284,748 Feb. 8, 1994) in view of JP 04-148669 May 21 1992.

The teachings of Mrocskowski et al are described previously.

Mrocskowski et al do not teach DNA.

JP 04-148669 teach a molecule securing device in which a chain is formed by using two aluminum electrodes installed on a substrate (see whole document). Between electrode 1 & 2 an electrical field is charged via leads 3 and 4 (see page 4 and Figs. 1 & 2). The device is applied to DNA molecules (see page 2).

One of ordinary skill in the art would have been motivated to apply teachings of DNA binding to Mrocksowski et al's device in order to detect DNA interactions. As it was well known in the art to detect DNA for disease mutations and as JP-04-148669 teach the successful use of DNA binding to provide a conducting connection between electrodes, it would have prima facie obvious to bind DNA in order to detect target DNA.

 Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mrocskowski et al (US5,284,748 Feb. 8, 1994) .

The teachings of Mrocskowski et al are described previously.

Mrocskowski et al do not teach explicitly a kit.

Mrocksowski et al's reagents into a kit in order to allow the practioner easy access to all the reagents to perform the assay. It was well known and commonly practiced in the art to incorporate reagents into kits. It would have been <a href="mailto:prima facie">prima facie</a> obvious to put Mrockowski et al's reagents into a kit so that one would be able to have the reagents to construct and perform the diagnostic assay efficiently.

8. Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mrocskowski et al (US5,284,748 Feb. 8, 1994) in view of Hisada et al (US5,914,505 June 22, 1999).

The teachings of Mrocskowski et al are described previously.

Mrocskowski et al do not teach explicitly of junction s forming diode.

Hisada et al teach a semiconductor integrated circuit for comprising first and second conductor and junction diode (see whole doc. esp.col.3).

One of ordinary skill in the art would have been motivated to combine Hisada et al's integrated circuit and Mrocskowski et al's device in order to provide for a multiarray device with high number of reaction sites. Mrocksowski et al already teaches a multiarray device (see Figure 8) and Hisada et al's semiconductor device provided internal circuits from malfunctioning (see col. 1line 43). It would have been <a href="mailto:prima-facie">prima-facie</a> obvious to combine Hisada et al's semiconductor device with Mrockskowski et al's device in order to provide device with highly multiple reaction sites with lower malfunctioning errors.

9. Claims 10,11,26-28 & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mrocskowski et al (US5,284,748 Feb. 8, 1994) in view of Yang et al (US5,563,424 Oct. 8, 1996)

The teachings of Mrocskowski et al are described previously.

Mrocskowski et al do not teach explicitly of polyaniline.

Yang et al teach polyanaline for advantages of better conduction (see whole doc. esp. col. 9 line 32).

One of ordinary skill in the art would have been motivated to apply Yang et al's polyaniline to Mrocskowski et al's device in order to provide increase efficiency in conduction. Yang et al state that polyanaline provides improved efficiency at lower operating voltages. It would have been prima facie obvious to apply Yang et al's polyanaline so that increased conduction would provide for better detection of the bound target.

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#### SUMMARY

10. No claims allowed.

#### Conclusion

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

Jeffrey Siew Primary Examiner March 24, 2002